

Applic. No. 10/010,244  
Amdt. Dated March 1, 2005  
Response to Office Action of November 1, 2004

Remarks/Arguments:

Reconsideration of the application is requested.

Claims 1 to 33 remain in the application. Claims 1 to 12 and 26 to 33 are subject to examination and claims 13 to 25 have been withdrawn from examination.

In items 1 to 7 on pages 2 to 4 of the above-identified Office action, claims 1, 2, 5, 6, 9 to 11, 27, and 29 to 33 have been rejected as being fully anticipated by U.S. Patent No. 5,037,021 to Mills et al. (hereinafter "Mills") under 35 U.S.C. § 102.

As will be explained below, it is believed that claims 1, 29 and 31 to 33 were patentable over Mills in their original form and, therefore, have not been amended to overcome Mills.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful.

Claim 1 calls for, *inter alia*, a medical method, including:

advancing a clip over body tissue, the clip having two arms each having a respective piercing portion and a bridge coupling the two arms, such that the body tissue

Applic. No. 10/010,244  
Amdt. Dated March 1, 2005  
Response to Office Action of November 1, 2004

is located between the two arms and such that the clip applies force to the body tissue.

Claim 27 calls for, *inter alia*, a medical method, including the steps of:

providing a clip having:

two arms each having a piercing portion; and

a bridge coupling the two arms.

Claim 29 calls for, *inter alia*, a medical method, including the steps of:

providing a clip having two arms each having a respective piercing portion and a bridge coupling the two arms.

As set forth above, each of the two arms of the clip has a respective piercing portion. Thus, claims 1, 27, and 29 provide for a clip with two piercing portions. Nowhere does Mills disclose or suggest a clip with two piercing portions and the Examiner's comments are silent with respect to this claimed feature. In fact, the Examiner clearly provides on page 3 that only "one of them is bent through the whole

Applic. No. 10/010,244  
Amdt. Dated March 1, 2005  
Response to Office Action of November 1, 2004

thickness of the *both portions of tissue* [see progression from Figure 5a to 5c]." Because Mills does not disclose a clip with two piercing portions, Mills cannot anticipate claims 1 or 29.

The Mills device shown in FIGS 5a to 5c only works if the "first upwardly extending section" is NOT a piercing portion - in other words, it functions as it is intended to function only if the "first upwardly extending section" does not pierce the tissue fold. See Mills at col. 6, line 16. It is further noted that suction through suction channel 204 cannot apply sufficient force to pierce the tissue with either the first upwardly extending section or the fourth section of the staple 209 because Mills requires the piston 205 to drive the fourth section "of the staple through the double layer of tissue so that its tip comes into contact with the anvil 260 and simultaneously deform[s] the remaining sections of the staple." Mills at col. 6, lines 20 to 28.

In the rejection, the Examiner comments about an "Attachment #2." This paper was not attached to the November 1, 2004 Office action. For the purposes of this response, it is assumed that this paper is the same as the "Attachment #2" in the April 15, 2004 Office action (it is noted that no Attachment #1 is present). If this assumption is incorrect,

Applic. No. 10/010,244  
Amdt. Dated March 1, 2005  
Response to Office Action of November 1, 2004

applicants respectfully request that the Examiner issue a new Office action including the "Attachment #2" and reset the date for this response. It is also noted that the Examiner mentions an "Arm A" in the last paragraph of page 2, but there is no indication of an "Arm A" in the Attachment #2.

The Examiner also rejects claims 31 to 33 as being fully anticipated by Mills.

Claims 31 and 32 provide that the clip is advanced "over body tissue folded on itself to form first and second portions of a fold disposed between the two arms and to apply a force to the folded body tissue, the folded tissue defining a longitudinal direction of the folded body tissue, the piercing portions of the two arms being initially oriented along the longitudinal direction." Emphasis added by applicants.

As set forth above, each of the two arms of the independent claims has a respective piercing portion, i.e., two piercing portions, and the Mills device has only one. Each of the two piercing portions of the present invention are "initially oriented along the longitudinal direction." Not only does the Mills device entirely fail to have or even suggest two piercing portions, Mills only has one portion initially oriented along the longitudinal direction - the **non-piercing**

Applic. No. 10/010,244  
Amdt. Dated March 1, 2005  
Response to Office Action of November 1, 2004

fourth portion. Thus, Mills has no piercing portion "initially oriented along the longitudinal direction" and cannot be said to anticipate claims 31 or 32.

For the reasons set forth above, Mills does not anticipate claim 1, 27, 29, or 31 to 33. Dependent claims 2 to 12, 26, and 28 are believed to be patentable as well because they all are ultimately dependent on claims 1 or 27.

As is known, conventional staples (whether medical or clerical) pierce sheets of a material orthogonal to the plane of the sheets and bend the prongs that pierce through and already extend beyond the sheets in a direction along the sheets to hold the sheets together and to, thereby, provide a compressing/holding force in the piercing direction, specifically, between the head of the staple and the bent-over tips.

FIGS. 5a to 5c of Mills clearly show that the Mills staple 209 is very similar to a staple from, for example, a SWINGLINE® desk stapler. In particular, the single portion of the Mills staple that is to pierce the tissue enters the tissue perpendicular to the tissue fold while an anvil is placed on the opposite side of the tissue. Then, after completely piercing the tissue 216, the piercing portion is bent

Appl. No. 10/010,244  
Amdt. Dated March 1, 2005  
Response to Office Action of November 1, 2004

subsequently by the anvil 260 disposed on the other side of the piston 205. Simply put, the Mills stapler pierces straight portions orthogonally through the tissue and subsequently bends the straight portions with an external device (anvil 260) positioned on the opposite side of the tissue to cause the clenching force.

The piercing portion of the invention of claims 1, 27, 29, and 31 to 33, however, do not perform in this way. The clip of these claims is advanced over the body tissue in a longitudinal direction of the body tissue to be clipped.

After advancing thereover, the piercing portion is caused to bend and, because of such bending, the tissue is pierced. Because Mills does not disclose the features of claims 1, 27, 29, 31, 32, or 33 it cannot be said to anticipate these claims.

In items 8 and 9 on pages 4 to 5 of the above-identified Office action, claims 1, 3, 4, 12, 26 and 33 have been rejected as being fully anticipated by U.S. Patent No. 5,582,611 to Tsuruta et al. (hereinafter "Tsuruta") under 35 U.S.C. § 102.

Claim 1 calls for, *inter alia*, a medical method, including:

Applic. No. 10/010,244  
Amdt. Dated March 1, 2005  
Response to Office Action of November 1, 2004

advancing a clip over body tissue, the clip having two arms each having a respective piercing portion such that the body tissue is located between the two arms; and

subsequently bending the piercing portion of at least one of the two arms through more than one half a thickness of the body tissue.

Claim 33 calls for, *inter alia*, a medical method, including:

a) advancing a clip over two thicknesses of body tissue, the clip having two arms each having a respective piercing portion and a bridge coupling the two arms, such that the body tissue is located between said two arms and such that the clip applies force to the body tissue; and

b) subsequently bending the piercing portion of at least one of the two arms through more than one of the thicknesses of said body tissue.

The Examiner contends on page 5 of the Office action that “[e]ach arm is bent through the entire thickness of the body tissue, such that the tips of the two arms contact each other [see progression from Figure 42B to Figure 42C].” Italics original; underline added by applicants. This conclusion is

Applic. No. 10/010,244  
Amdt. Dated March 1, 2005  
Response to Office Action of November 1, 2004

incorrect because the "body tissue" that is being used by the Examiner is not the same "body tissue" that is defined in claims 1 and 33 and, therefore, cannot be analogized to the "body tissue" set forth in each of claims 1 and 33.

Each of these independent claims defines what the phrase "body tissue" means.

First, claim 1 provides that a clip is advanced over a feature referred to as *body tissue* so that the *body tissue* is located between the two arms. This means that whatever tissue that exists between the two arms is the *body tissue* of claim 1. Later in claim 1, one piercing portion is bent "through more than one-half a thickness of [this] *body tissue*." Looking at FIG. 25 of the instant application, for example, it can be clearly seen that a piercing portion is bent through more than one half of the thickness of the tissue that exists between the two arms. In stark contrast, the staple half of Tsuruta clearly is never bent through more than one half of the thickness of tissue between the two arms of staple 22. FIG. 39C explicitly shows that the *maximum* distance that an arm of the staple 22 is bent **is no greater than** half of the thickness of tissue between the two arms of the staple 22.

Appl. No. 10/010,244  
Amdt. Dated March 1, 2005  
Response to Office Action of November 1, 2004

Second, claim 33 provides that a clip is advanced over a feature referred to as "two thicknesses of body tissue" so that this double thickness of body tissue is "located between said two arms." This means that whatever tissue that exists between the two arms is *two thicknesses of body tissue*. Later in claim 33, one piercing portion is bent "through more than one of said [two] thicknesses of [this] body tissue." Looking at FIG. 25 of the instant application, for example, it can be clearly seen that a piercing portion is bent through more than one of the two thicknesses of folded tissue that exists between the two arms. In stark contrast, however, the staple half of Tsuruta clearly is never bent through more than one of the two thicknesses of tissue between the two arms of staple 22. FIG. 39C explicitly shows that the *maximum* distance that an arm of the staple 22 is bent **is no greater than** one thickness of body tissue existing between the two arms of the staple 22.

As shown clearly in Tsuruta, especially in FIGS. 39C, 42C, 43C, 49C, 53D, 55D, 59A, and 59B, each side of the staple 22a, 22b only pierces to a point where one side 22a of the staple 22 touches the other side 22b. Therefore, each piercing side only pierces *up to the half-way point* of the tissue therebetween, but not more. This limited extent is a required limitation of Tsuruta and nowhere does Tsuruta disclose or

Applic. No. 10/010,244  
Amdt. Dated March 1, 2005  
Response to Office Action of November 1, 2004

suggest having either side (22a, 22b) of the staple 22 pierce more than half of the way through the tissue between the two sides 22a, 22b. In fact, the Examiner admits on page 5 of the Office action that "*the tips of the two arms contact each other.*" Emphasis original. Thus, each arm prevents the other arm from piercing past the half-way point. It is noted that FIGS. 57C, 60B, 60C, 62B, and 62C show embodiments where the tips of the staple are not even touching - thus, they cannot even be considered as entirely pierce through even one of the two layers of tissue present between the tips.

The Examiner states that Tsuruta discloses, in FIGS. 42 and 43, that the Tsuruta "clip (22) has two arms and bridge coupling the arms, as shown in Figure 61" and also states that "the clip applies force to the body tissue." However, the Examiner incorrectly contends that "[e]ach arm is bent through the entire thickness of the body tissue such that the tips of the two arms contact each other." (Emphasis original.)

The final rejection is entirely silent on the Tsuruta clip 22 "advancing over" any body tissue. This is because the Tsuruta clip does not disclose or suggest advancing the clip 22 over body tissue. Tsuruta does not "advance over" the tissue because, as shown clearly in FIGS. 39A to 39C, 42A to 42C, 43A to 43C, 49A to 49C, 53A to 53D, 55A to 55D, 59A to 59B, 60A to

Applic. No. 10/010,244  
Amdt. Dated March 1, 2005  
Response to Office Action of November 1, 2004

60C, and 62A to 62C, the Tsuruta clip 22 only pierces into the tissue. In contrast, claims 1 and 33 clearly provide that a clip is advanced over the body tissue between the two arms. Because Tsuruta does not disclose or suggest such a feature, it cannot be said to anticipate claims 1 or 33.

In items 10 and 11 on pages 5 to 6 of the above-identified Office action, claims 7 and 8 have been rejected as being obvious over Mills in view of U.S. Patent No. 5,571,116 to Bolanos et al. (hereinafter "Bolanos") under 35 U.S.C. § 103.

Insofar as claim 1 is believed to be allowable, and due to the fact that claims 7 and 8 ultimately depend upon claim 1, the rejection of these claims is now believed to be moot.

Just like Mills, Bolanos' staple 30 is similar to a conventional desktop stapler. Specifically, the portion of the staple 30 that is to pierce the tissue enters the tissue perpendicular to the tissue fold while an anvil 26 is placed on the opposite side of the tissue (see anvil recesses 33 in FIG. 6A, 6B, and 8). Then, after completely piercing the tissue, the pierced and orthogonally extending portion is bent by the anvil 26 disposed on the other side of the staple ejector 28. See Bolanos at FIGS. 6B and 8. Nowhere does Bolanos disclose or suggest "advancing a clip over body

Applic. No. 10/010,244  
Amdt. Dated March 1, 2005  
Response to Office Action of November 1, 2004

tissue" as set forth in claim 1. Thus, Bolanos cannot suggest claim 1 of the instant application, let alone claims 7 and 8.

It is accordingly believed to be clear that none of the references, whether taken alone or in any combination, either show or suggest the features of claims 1, 27, 29, 31, 32, or 33. Claims 1, 27, 29, 31, 32, and 33 are, therefore, believed to be patentable over the art. The dependent claims are believed to be patentable as well because they all are ultimately dependent on claims 1, 27, or 29.

ALLOWANCE OF WITHDRAWN CLAIMS:

In the election of species requirement, the Examiner stated that upon allowance of a generic claim, applicants would be entitled to consideration of the claims of Species 2. It is noted that the Species 2 feature of the method of applying a clip with unconnected arms can be read on claim 1 because claim 1 is broad enough to encompass both connected and unconnected clip arms. See new claim 28. Therefore, claim 1 is generic to Species 2 and claims 13 to 18 should be allowed as well.

In view of the foregoing, reconsideration and allowance of claims 1 to 18 and 26 to 33 are solicited.

Applic. No. 10/010,244  
Amdt. Dated March 1, 2005  
Response to Office Action of November 1, 2004

In the event the Examiner should still find any of the claims to be unpatentable, counsel would appreciate receiving a telephone call so that, if possible, patentable language can be worked out. In the alternative, the entry of the amendment is requested, as it is believed to place the application in better condition for appeal, without requiring extension of the field of search.

If an extension of time for this paper is required, petition for extension is herewith made.

Please charge the extension fee for response within a period of one (1) month pursuant to Section 1.136(a) in the amount of \$120.00 in accordance with Section 1.17 to the Deposit Account of Feldman Gale, P.A., No. 502524. Please charge any other fees that might be due with respect to Sections 1.16 and 1.17 to the Deposit Account of Feldman Gale, P.A., No. 502524.

Respectfully submitted,

For Applicants  
GLM.com

March 1, 2005

Gregory L. Mayback  
Reg. No. 40,719

Feldman Gale, P.A.  
201 S. Biscayne Boulevard, 19<sup>th</sup> Floor  
Miami, FL 33131-4332  
Tel: 305.358.5001  
Fax: 305.358.3309